POMERANTZ LLP
Joshua B. Silverman (*pro hac vice*)
Louis C. Ludwig (NJ 043582008)
10 South LaSalle St., Ste. 3505
Chicago, IL 60603
Telephone: (312) 377-1181
jpsilverman@pomlaw.com
lcludwig@pomlaw.com

FREEDMAN NORMAND FRIEDLAND LLP
Ivy T. Ngo (*pro hac vice*)
Velvel (Devin) Freedman (*pro hac vice*)
1 SE 3rd Ave., Suite 1240
Miami, Florida 33131
Telephone: (786) 924-2900
ingo@fnf.law
vel@fnf.law

Counsel for Lead Plaintiff and the Class

- additional counsel on signature page –

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE CORMEDIX INC. SECURITIES LITIGATION	Case No. 2:21-cv-14020-JXN-CLW CLASS ACTION Hon. Julien Xavier Neals
This Document Relates To:	**Motion Day: September 3, 2024**

LEAD PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE THIRD AMENDED CONSOLIDATED CLASS ACTION COMPLAINT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page(s)**

Rules

Statutes

Plaintiff hereby opposes Defendants' motion to dismiss as follows:[1]

PRELIMINARY STATEMENT

During the Class Period, Defendants inflated the price of CorMedix stock by touting their ability to commercially manufacture the Company's flagship product, an antibacterial and antifungal catheter lock solution called "Neutrolin" (called "DefenCath" in the U.S.), pursuant to U.S. Food and Drug Administration ("FDA") standards. All the while, Defendants knew, but did not disclose to investors, that a 2018 audit the Company procured of its chosen commercial manufacturing organization ("CMO"), ROVI Contract Manufacturing, S.E. ("ROVI"), had recommended that ROVI not be used because it would not be able to pass an FDA inspection.

Nevertheless, Defendants pushed ahead with ROVI as CMO without warning investors of the known higher risk of obtaining FDA approval and capitalized on CorMedix's inflated stock price by raising more than $60 million through two public offerings of Company shares. These ill-gotten gains were made possible by Defendants' misleading statements to CorMedix investors, downplaying early

[1] "Plaintiff" is Lead Plaintiff John C. Levon and "Defendants" are CorMedix Inc. ("CorMedix" or the "Company") and the "Individual Defendants", comprised of Khoso Baluch, Robert Cook, Matthew David, Phoebe Mounts, John L. Armstrong, and Joseph Todisco. The "Class Period" runs from October 16, 2019 to August 8, 2022, inclusive. Paragraph citations ("¶") refer to the numbered paragraphs of Plaintiff's Third Consolidated Amended Class Action Complaint ("Complaint") (ECF No. 97). "DM" refers to the pages of the Memorandum in Support of Defendants' Motion to Dismiss the Third Amended Consolidated Class Action Complaint (ECF No. 104-1). Unless otherwise noted, internal citations are omitted and emphasis is added.

concerns raised by the FDA while touting the Company's success in other markets and the strength of its team. For example, Defendants falsely reassured investors that "[o]ur press release of July 9 … ***was intended to be a clear signal from CorMedix to the life science investors that we understand the importance of manufacturing data and that we are on top of it.***" ¶88. In reality, the New Drug Application ("NDA") that CorMedix submitted confidentially to the FDA for DefenCath was critically defective, exposed CorMedix's lack of consideration for FDA's requirements, and laid bare CorMedix's failure to oversee and remedy multiple issues at its designated manufacturing facility.

Due to the inadequate Chemistry, Manufacturing, and Control ("CMC") information Cormedix provided to the FDA and the lack of commercial readiness of its CMO for the U.S. market, the FDA rejected DefenCath via a Complete Response Letter (or "First CRL") on February 26, 2021. Specifically, ROVI "was found inadequate following a 704(a)(4) based review" and "inadequate in-process controls were proposed for … the drug product manufacturing process." ¶20. As a result, Defendants had to disclose manufacturing deficiencies resulting in a CRL on March 1, 2021, shocking investors who had no reason to expect such issues. Those revelations caused CorMedix's share price to drop sharply, damaging Plaintiff and other investors.

Instead of coming completely clean, Defendants continued to falsely reassure investors ***for nearly 12 months*** that all manufacturing deficiencies had been resolved, and resubmitted the DefenCath NDA in February 2022. Defendants, however, had not actually resolved the identified manufacturing deficiencies and, in August 2022,

CorMedix received ***another CRL*** (or "Second CRL") for the same non-compliant CMO – and for a non-compliant active pharmaceutical ingredient ("API") manufacturer. CorMedix's stock price fell even more sharply than it did after the First CRL. This steeper drop was unsurprising: investors had consistently been told that the issues with the NDA were minor and many would be fixed in weeks, thereby causing Plaintiff and the putative class to suffer additional losses and damages.

Despite being required by FDA regulations to ensure compliance of its CMO with FDA standards, Defendants misrepresented or omitted known, then-existing manufacturing problems imperiling the DefenCath NDA. In their motion, Defendants rely on the same misleading language challenged in the Complaint to argue that their Class Period statements regarding the NDA for CorMedix's core product were truthful, mere opinions, or protected by the Private Securities Litigation Reform Act of 1995 ("PSLRA")'s safe harbor. Yet binding precedent rejects the notion that Defendants can insulate their statements from liability with nothing more than artful phrasing.

In making their public statements, Defendants possessed the requisite state of mind (or *scienter*) for recklessness because they knew, or had access to, information contradicting those statements. Lastly, Plaintiff's loss causation allegations easily satisfy the corresponding pleading standard, which requires only that Plaintiff allege a causal connection between Defendants' conduct and his (and the Class's) losses.

Plaintiff's claims are sufficiently pled, with ¶¶309-20 addressing Defendants' fraudulent misrepresentations as set forth in ¶¶90, 92-96, 98-101, 178-217, and ¶¶321-

25 showing the Individual Defendants' secondary liability as control persons for those misrepresentations and alleging the factual basis for each control relationship.

Accordingly, Defendants' motion should be denied in its entirety.

STATEMENT OF RELEVANT FACTS

A. CorMedix's Core Focus on Obtaining FDA Approval for Neutrolin

At all relevant times, CorMedix primarily focused on securing FDA approval for its lead product candidate, Neutrolin (branded DefenCath), a solution for catheter-related infections. ¶2. To obtain FDA approval, CorMedix had to submit an NDA and through that process, show that the methods used to manufacture DefenCath and the controls used to maintain its quality adequately preserve its identity, strength, quality, and purity. ¶3. In particular, CorMedix was responsible for maintaining a demonstrably consistent manufacturing process, and evaluating, overseeing and managing any third-party CMOs. *Id*. To that end, Cormedix selected ROVI as CMO for DefenCath in 2017, and commissioned an audit of ROVI in 2018. ¶¶4-5. Although the audit recommended the non-use of ROVI because it would not pass an FDA inspection, Cormedix pushed ahead with ROVI without warning investors about the audit or its conclusions. ¶¶5, 40.

Instead, in order to assuage investor concerns, Defendants claimed to have validated the manufacturing process to meet FDA standards. Specifically, in August 2019, Defendant Armstrong – EVP of Technical Operations since 2017 – assured investors that they "have successfully carried out technical transfer and validation of the manufacturing process, which has enabled the successful production of product at

three different manufacturing sites …. And importantly, the key members of my staff, including me, have in our past experience, successfully submitted multiple NDAs that were ultimately approved." ¶6.

Because of that experience, on the first day of the Class Period, October 16, 2019, Defendants claimed that Cormedix had all the data, processes and controls – including the manufacturing information – needed to submit a successful NDA and that "***[t]he FDA was supportive of Neutrolin's proposed manufacturing program, including the [API], the container closure and testing***," ¶7. The market reacted favorably, causing the Company's stock price to increase by over 9%. *Id*. A few weeks later, on November 7, 2019, the FDA privately instructed CorMedix to identify all manufacturing facilities associated with DefenCath and to ensure their preparedness for inspection by the time the Company formally applied for FDA approval. ¶8.

The next week, during the first earnings call of the Class Period, on November 14, 2019, Defendant Armstrong reiterated that the FDA supported CorMedix's manufacturing efforts and noted that the "FDA did request some additional data which we are working to complete." ¶9. The request indicated that there was an issue in the Company's CMC module that concerned the FDA. ¶10. But Armstrong did not elaborate on the specific nature of the requested "additional data" – of which he was aware – and instead quickly reassured investors of the Company and its manufacturing team's proven "***breadth and depth in the requirements for sourcing, manufacturing, distribution and quality assurance***" based on its five-year track record of successfully

manufacturing and selling Neutrolin outside the U.S. and completing "***technical transfer and validation of the manufacturing process***" which had enabled "***the successful production of product at three different manufacturing sites***." *Id*. As the market absorbed these, and other positive statements, indicating that Cormedix's manufacturing was on track for a successful NDA submission, the Company's stock jumped 24% over the next two trading days. ¶11.

When Cormedix began submitting the NDA modules for rolling review in March 2020, the FDA engaged the Company in dialogue to determine, *inter alia*, whether the facility that would be manufacturing, processing, packaging, and holding Neutrolin met FDA standards designed to assure its continued safety, quality, and purity. ¶12. In May 2020, the Company formed a wholly owned subsidiary in Spain, CorMedix Spain, S.L.U., apparently to observe its CMO and manufacturer of heparin, a key API. ¶13.

On July 8, 2020, Defendants highlighted their ability to submit a complete NDA to investors, portraying CorMedix and its CMO as having successfully collected the data required to meet FDA standards so all that was left was "work[ing] through the [CMC] information" and approval. ¶¶14, 98. On this news, the Company's stock price increased 7%. ¶14.

Throughout the rest of the Class Period, Defendants continued to tout NDA milestones that maintained or increased the Company's stock price, while highlighting that the FDA "had not identified any potential review issues":

- 8/31/20: CorMedix announced that the FDA had accepted the

DefenCath NDA for filing and granted it Priority Review with a Prescription Drug User Fee Act date of February 28, 2021.

- 11/18/20: CorMedix announced that an advisory committee meeting for the DefenCath NDA was not needed. ¶15.

Capitalizing on its inflated stock price, CorMedix announced a public offering on July 29, 2020, issued on November 27, 2020 and supplemented on August 12, 2021. ¶16.

In total, the Company sold 832,676 shares of common stock in the offering at a weighted average price of $8.69 per share, realizing net proceeds of approximately $7.0 million during 2020. ¶102. And, during the first nine months of 2021, the Company sold an aggregate of 3,737,862 shares of common stock at an average price of $11.10 per share, realizing net proceeds of approximately $41.5 million. *Id*.

B. Defendants Continue to Deceive Investors About the NDA

When touting their submission of the DefenCath NDA to the market, Defendants failed to disclose that they had submitted the NDA without fully verifying its completeness or maintaining sufficient processes and controls to ensure the Company's contracting facilities had met, and would continue to meet, FDA standards for commercial readiness. ¶19. Defendants, not the third-parties they contracted with, were ultimately responsible for ensuring processes were in place to assure the control of outsourced activities (*e.g.*, manufacturing) and the quality of purchased substances (*e.g.*, heparin), based on well-established current Good Manufacturing Practice ("cGMP") standards and the Company's ongoing dialogue with the FDA. *Id*. In the end, Defendants were responsible for what they conveyed to CorMedix investors.

Instead of being candid with investors about known CMC problems and their failure to verify cGMP compliance, Defendants spoke of the NDA's success as a foregone conclusion. For example, as early as August 10, 2020, Baluch claimed that CorMedix was already "***making necessary preparations for the launch of DefenCath in the U.S. hemodialysis market, following FDA approval.***" ¶202. Defendants also positively touted "the level of engagement between FDA and the CorMedix team" and misrepresented (i) that the DefenCath NDA was "on track" for approval; (ii) conditions that had already come to pass as hypothetical "risks"; and (iii) whether CorMedix's SEC filings fairly presented, "in all material respects, the financial condition and results of operations of the Company." *See e.g.*, ¶¶96, 101, 121-22, 133, 192, 215, 233.

Specifically, Defendants never revealed severe manufacturing concerns raised by their own audit and by the FDA to CorMedix during an October 2019 CMC meeting. ¶103. Nor did they inform investors that the FDA's request for more information was based on identified deficiencies in the manufacturing process, on top of mounting deficiencies at their CMO's manufacturing facilities. *Id*. Because Defendants failed to ensure that their CMO was cGMP-compliant, the FDA observed numerous deficiencies relating to the CMO's facilities and the CMC information provided by the Company. *Id*. These problems were known by Defendants, and the FDA's concerns were shared with the Company. Defendants simply chose not to be candid with investors.

By July 9, 2020, Defendants knew or recklessly ignored that their CMO would be "procuring a new production line and equipment for compounding, filling,

automatic visual inspection and labeling" for Moderna's COVID-19 vaccine at the facility which was manufacturing DefenCath. ¶163. Well-understood FDA guidelines made clear to Defendants that they had to give information about any new production line and/or equipment at the facility manufacturing DefenCath to the FDA – even if it was unrelated to DefenCath. *Id*. They failed to do so. And they stayed silent on the manufacturing deficiencies, thus maintaining CorMedix's artificially high share price.

C. Investors Slowly Learn the Truth

Due to the observed deficiencies, the FDA could not grant approval. Instead, the FDA issued the First CRL to Cormedix on February 26, 2021, explaining that the DefenCath NDA could not (and would not) be approved until the manufacturing deficiencies at the Company's CMO were fully remedied. ¶20. The FDA detailed that ROVI "was found inadequate following a 704(a)(4) based review; and (2) inadequate in-process controls were proposed for … the drug product manufacturing process." *Id*.

Because the Company had not previously come clean about its manufacturing deficiencies, investors were shocked when, on March 1, 2021, CorMedix issued a press release disclosing that the "FDA noted concerns at the third-party manufacturing facility after a review of records requested by FDA and provided by the manufacturing facility." ¶21. The same release further explained that the "FDA is requiring a manual extraction study to demonstrate that the labeled volume can be consistently withdrawn from the vials despite an existing in-process control to demonstrate fill volume within specifications." *Id*. CorMedix shares fell nearly 40% in response to the new revelation,

which analysts confirmed was a "***surprise***." ¶22. Yet, Defendants continued to conceal the negative audit report they received assessing ROVI's facilities, and assured investors that ROVI "manufactures drugs sold in the U.S.[,] implying some level of FDA inspection in the past that passed FDA's standards," and that it "is experienced in handling drug/device combos similar in scope to DefenCath." ¶23.

The following week, Defendants continued to downplay the issues raised in the First CRL during the Company's call with analysts and investors on March 9, 2021, noting that "one deficiency result[ed] from the proposed future installation of new equipment, but it was apparently not clear to FDA that the equipment is unrelated to the manufacturer of DEFENCATH", and that the additional requested manual extraction study and airflow visualization study would be "completed in the next several weeks." ¶24. Based on these and other statements, the market believed that "the manufacturing issues are straightforward and can be resolved within weeks." *Id*.

But that was not true. As investors learned on April 14, 2021, CorMedix could not resubmit an NDA until 3Q21 because it had to take additional steps to address known deficiencies in DefenCath's manufacturing process, including "the qualification of the filling operation [that] may necessitate adjustments in the process and generation of additional data on operating parameters for manufacture of DefenCath." ¶25. The Company's shares fell 18% in response. *Id*.

After "[k]ey representatives from both CorMedix and its CMO participated in a meeting…to address the deficiencies noted in the [First] CRL," Defendants assured

investors they were finally aligned with the FDA. ¶26. As a result, investors understood "there [wa]s a clear resolution plan agreed upon with the FDA to address the manufacturing CRL," and "anticipate[d] NDA resubmission in the next few months … followed by FDA decision on the need for a site visit … in late 3Q21 or 4Q21[.]" *Id*.

But then, on May 13, 2021, CorMedix disclosed it could not even resubmit its NDA until 4Q21 because "additional process qualification will be needed with subsequent validation to address the [CMC] deficiencies identified by FDA," causing the Company's stock price to fall nearly 20%. ¶27. Still, Defendants remained positive about the Company and its CMO's ability to resolve the manufacturing deficiencies and resubmit the NDA by the end of the year, touting that "***we have the right team and appropriate resources in place to resolve the third-party manufacturing deficiency***" and "***we are on schedule to be able to resubmit the CorMedix NDA in [4Q21]***." ¶28.

Investors learned on September 7, 2021 that not only had the Company "encountered delays at its third-party [CMO]," but "the timeline for [it] and the CMO to address deficiencies at the facility that are required for resubmission of the DefenCath NDA is uncertain[.]" ¶29. In response, CorMedix's stock price fell over 27%. *Id*. The continued delays in resolving long-known manufacturing deficiencies informed investors that the problems were more severe than initially disclosed, and that CorMedix did not have the "right team" to do the job. ¶137. That was confirmed on October 4, 2021, when CorMedix announced that Baluch was immediately retiring from his role as CEO and resigning from the board of directors (after being "at the

helm" for over five years), and Armstrong was also retiring. *Id*.

Despite previously assuring investors that the Company and its CMO already had the "right team" to resolve the manufacturing deficiencies, Mounts admitted on November 4, 2021 that CorMedix needed to "engage [a] team of external consultants to provide additional expertise on FDA's expectations for addressing the specific deficiencies at the manufacturing facility, and to assist in preparations for a pre-approval inspection." ¶138. Such statements were intended to, and did, reassure investors that the Company had finally ensured cGMP compliance at its CMO, despite Defendants having known *for years* that such compliance was mandatory. Based on these assurances, investors took a positive view of CorMedix's resubmission of the DefenCath NDA on February 28, 2022. ¶32. But investors had once again been misled.

On August 4, 2022, CorMedix received another CRL, which, like its predecessor, cited the long-known but unresolved CMC problems. ¶33. According to the Company, the FDA explained in the Second CRL that "the status of the drug product manufacturing facility was ***again*** found unacceptable[,]" as was "the proposed commercial manufacturer of the heparin sodium drug substance." *Id*. Specifically, in sharp contrast to the Company's prior six months of reassurances to the market, unresolved manufacturing deficiencies were so severe they had persisted at its CMO's facilities, ***and*** it had improperly attempted to resolve a customs hold-up involving its existing heparin supplier by adding another supplier without properly disclosing the new supplier to the FDA or ensuring that both suppliers used the same vial size. ¶34.

CorMedix further admitted that the Second CRL warned "that the DefenCath NDA cannot be approved until deficiencies recently conveyed to the [CMO] and the supplier of the [API] heparin during inspections are resolved to the satisfaction of FDA." ¶35. It also conceded that the CMO it selected, ROVI, needed "an ***independent*** CGMP consultant to expedite the implementation of corrective actions," confirming that Defendants had never validated ROVI's compliance as they had assured investors. *Id*. Its oversight of ROVI thus had been insufficient. Investors were stunned. The Company's stock price plummeted over 57% in response. ¶36.

PLAINTIFF ADEQUATELY ALLEGES §10(b) VIOLATIONS

A. Legal Standards on Rule 12(b)(6) Motions to Dismiss

To withstand a motion to dismiss under Federal Rule of Civil Procedure ("Rule") 12(b)(6), a plaintiff "need only allege 'enough facts to state a claim to relief that is plausible on its face.'" *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 46 n.12 (2011) (*quoting Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The question is whether the plaintiff is "entitled to offer evidence to support the claims," not whether it "will ultimately prevail." *U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 302 (3d Cir. 2011). On a Rule 12(b)(6) motion to dismiss, courts "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, [it] may be entitled to relief." *Fleisher v. Standard Ins. Co.*, 679 F.3d 116, 120 (3d Cir. 2012).

The PSLRA and Rule 9(b) impose two additional pleading standards to claims

under §10(b) of the Securities Exchange Act of 1934. First, misstatements must be alleged with particularity. *See Institutional Invs. Grp. v. Avaya, Inc.*, 564 F.3d 242, 252-53 (3d Cir. 2009). This calls for allegations to "provide assurance that plaintiff has investigated the alleged fraud and reasonably believes that a wrong has occurred," not an "exhaustive cataloging of facts." *Medtronic Ave, Inc. v. Bos. Sci. Corp.*, 2001 WL 652016, *2 (D. Del. Mar. 30, 2001). And where, as here, the factual information is peculiarly within defendants' knowledge or control, the particularity rules are relaxed. *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1418 (3d Cir. 1997).

Second, the alleged facts must support a strong inference of scienter. *See* 15 U.S.C. §78u-4(b)(2). That standard is met where a reasonable person would "deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged," but it need not be "the most plausible of competing inferences." *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 324 (2007). And the scienter of executives acting within the scope of their employment is imputed to the company. *Carmack v. Amaya Inc.*, 258 F. Supp. 3d 454, 468 (D.N.J. 2017).

B. Material Misstatements and Omissions are Sufficiently Identified

1. The misstatements and omissions about the then-current state of manufacturing deficiencies

Plaintiff has properly pled that Defendants made direct misstatements about the then-current adequacy of the Company's manufacturer. Just before the Class Period began, Armstrong claimed to "understand Neutrolin's manufacturing, technical,

analytical processes as well as the quality controls and the systems that go with it.… And importantly, the key members of my staff, including me, have in our past experience, successfully submitted multiple NDAs that were ultimately approved." ¶¶6, 88. At the time, he further claimed, on behalf of the entire Company, to "understand the importance of manufacturing data and that we are on top of it." ¶88.

That claimed understanding and experience led investors to believe Defendants' distortions throughout the Class Period, including, *inter alia*, that:

- 11/14/19: "[T]he drug product manufacturer ... is in place and ***processes have been established and appropriate validation testing completed to enable manufacture of launch quantities.***" ¶185.
- 3/9/21: The First CRL disclosed on March 1, 2021 posed minimal hurdles, as one deficiency would be resolved within "several weeks" and the other was "unrelated to the manufacture[]" of DefenCath. ¶223.
- 4/14/21: CorMedix had, ***in April 2021***, following receipt of the First CRL, "***[s]uccessfully concluded*** … validation of the drug product manufacturing process, which has enabled production at 2 different manufacturing locations[,]" and "[l]aunch quantities are already in production[.]" ¶240.
- 2/28/22: ***"we and the manufacturer have adequately addressed the concerns the [FDA] identified in the CRL and PAAL."*** ¶266.
- 3/28/22: "***CorMedix and [its CMO] have adequately addressed the concerns the [FDA] identified during the review of the original NDA***...." ¶147.
- 6/15/22: CorMedix was "going to work closely with [its] CMO for any observations that are related to DefenCath" so the only risk in the FDA inspection of the manufacturing operations were "observations that didn't involve [its] product." ¶279. But its "***highly reputable European manufacturer***" would "work with the FDA on, ***if necessary, improving any compliance concerns FDA could raise***." *Id*.

These statements are actionable because Plaintiff "ha[s] alleged sufficient facts

that if accepted as true, establish knowledge on the part of the Defendants that [the] statements ... were false or misleading or omitted a material fact." *Gargiulo v. Isolagen, Inc.*, 527 F. Supp. 2d 384, 389 (E.D. Pa. 2007). Those facts include Defendants' concealment of the severity of the FDA's concerns during CorMedix's October 2019 CMC meeting and that the FDA's resulting request for more information was based on identified deficiencies in the manufacturing process and mounting deficiencies at the CMO's manufacturing facilities. ¶¶103, 186. Then, after the First CRL, those facts include that CorMedix could not quickly resolve the manufacturing deficiencies to comply with cGMP standards. ¶¶149, 221, 228, 241, 269, 280. Defendants chose to speak about the then-present state of manufacturing capabilities related to the DefenCath NDA, and thus had to disclose material facts related to it. *See Kline v. First W. Gov't Sec., Inc.*, 24 F.3d 480, 490-91 (3d Cir. 1994) (finding actionable omissions where, as here, executives "elected to speak" but "failed to include ... information that, if included, would have undermined the conclusions" in the alleged misstatements).[2]

[2] Defendants improperly seek factual determinations at odds with the Complaint's well-pled allegations, which must be accepted as true at this stage. *See Fleisher*, 679 F.3d at 120. Specifically, Defendants seek merits determinations as to i) whether certain FDA forms and correspondence are "final" and therefore require disclosure and (ii) whether, despite Plaintiff's detailed allegations demonstrating Defendants' knowledge and obligation to assess CMO deficiencies, they might have remained ignorant of blatant problems occurring at the CMO. *See* DM at 9, 15, 23, and n.10. Such fact-intensive disputes are inappropriate on a motion to dismiss. *See In re Viropharma Inc. Sec. Litig.*, 21 F. Supp. 3d 458, 470 n.20 (E.D. Pa. 2014) (denying motion to dismiss and rejecting defendants' alternative version of the facts, noting plaintiff is entitled "to discovery to flesh out the truth of the narrative").

2. The misstatements and omissions about being "on track"

The Complaint cogently pleads that while repeatedly assuring investors that the DefenCath NDA was on track for FDA approval, Defendants withheld serious known risks about the NDA's sufficiency and their CMO's manufacturing capabilities. ¶¶107-38. During the Class Period, Defendants told the market, *inter alia*, that:

- 4/22/20: "We have ***remained on schedule*** towards an anticipated approval in the second half of 2020, subject of course to possible delays at FDA due to the coronavirus pandemic." ¶194.
- 5/11/20: "[W]e are ***maintaining our guidance*** for an anticipated decision on approval of the NDA in the second half of 2020." ¶196.
- 8/31/20: "[W]e look forward to ***continuing to work together [with the FDA] expeditiously*** to complete the review of the Defencath NDA to address an unmet medical need." ¶207.
- 11/5/20: CorMedix "has not been informed of any delays by the FDA in the review of the NDA…" ¶100.
- 8/12/21: "CorMedix ***remains on schedule*** for a potential NDA approval during the second half of 2020." ¶187.
- 5/12/22: "[I]n terms of activities that we are currently undertaking, ***we are doing right now all the typical prelaunch planning***." ¶¶153, 277.
- 6/15/22: "So ***from everything that we can see***, I'm optimistic that ***everything is moving in the right direction***." ¶279.

Defendants' decision to speak extensively and continually about the claimed timeline for FDA approval created a corresponding duty to reveal the issues at the manufacturing facility impeding that timeline. *See, e.g.*, *In re Digital Island Sec. Litig.*, 357 F.3d 322, 329 n.10 (3d Cir. 2004) (duty to affirmatively disclose "'may arise when there is ... an inaccurate, incomplete or misleading prior disclosure'"). More directly,

Defendants' "on track" statements are actionable because they falsified the then-current status of the DefenCath NDA. *See In re Cigna Corp. Sec. Litig.*, 2005 WL 3536212, *11 (E.D. Pa. Dec. 23, 2005) (finding statement that "we are on track with our own schedule" actionable where company was not "on track"); *see also Frater v. Hemispherx Biopharma, Inc.*, 996 F. Supp. 2d 335, 348-49 (E.D. Pa. 2014) (defendants "systemically misled investors about the key components of the … NDA and the nature of FDA feedback while presenting predictions about FDA approval … that [they] should have known were unreasonable under the circumstances").[3]

Third Circuit courts have repeatedly affirmed the actionability of alleged misstatements that selectively disclosed to investors what data was provided to the FDA. *See Tomaszewski v. Trevena*, Inc., 482 F. Supp. 3d 317, 331 (E.D. Pa. 2020) (omissions actionable where defendant knew that NDA would be deficient because he knew that Trevena's studies did not conform to FDA requirements); *see also In re Celgene Corp. Sec. Litig.*, 2019 WL 6909463, *18 (D.N.J. Dec. 19, 2019) ("that Defendants told investors about the positive clinical study results but failed to disclose

[3] Accordingly, *In re Amarin Corp. PLC Sec. Litig.*, 2021 WL 1171669 (D.N.J. Mar. 29, 2021), in which "the challenged statements do not put 'in play' the allegedly omitted information" is inapposite, as is *In re Genzyme Corp. Sec. Litig.*, 754 F.3d 31 (1st Cir. 2014), in which the alleged omission was not related to the drug at issue. *See* DM at 20, 22. Here, investors did not know that CorMedix kept from the FDA that its CMO added a new production line and equipment to the same facility proposed to manufacture DefenCath, or that CorMedix added another heparin supplier without disclosing the new supplier to the FDA or validating identical vial size and fill quantity. ¶¶34, 163, 165-72. Defendants' failure to inform the FDA added risk to the DefenCath NDA, and left investors holding the bag when that risk materialized. ¶¶35-36, 164, 173.

the Metabolite discovery was misleading"); *SEB Inv. Mgmt. AB v. Endo Int'l, PLC*, 351 F. Supp. 3d 874, 898 (E.D. Pa. 2018) (falsity alleged where defendants failed to disclose unfavorable data that would inform the FDA's decision).

3. The misstatements and omissions claiming FDA support

Defendants repeatedly and falsely informed investors that the FDA was inclined to approve DefenCath, despite knowing that its observations at the manufacturing facility made FDA approval a longshot at best. Defendants implied to investors that the FDA's observed deficiencies were minor by stating, *inter alia*, that:

- 10/16/19 & 11/14/19: "***The FDA was supportive of Neutrolin's proposed manufacturing program***...." ¶¶178, 181.
- 11/14/19: "As our press release of 16 October indicated the outcome of our interaction with the FDA was very positive. ***FDA was supportive of the core manufacturing processes for the drug product*** and the active pharmaceutical ingredients for the inclusion as part of the NDA submission." ¶¶93, 184.
- 11/5/20: The FDA "noted that … ***it had not identified any potential review issues at this time***." ¶211.
- 6/15/22: Responding "***Yes, yes***" to the question of "has the company addressed all the questions [from the FDA] appropriately?" ¶154.

The law is clear: Defendants' blatant misstatements, which directly contradicted what they then knew, are actionable. *See SEB*, 351 F. Supp. 3d at 898 (claims sustained where defendants, while "instilling hope in their investors … failed to disclose the unfavorable data that would inform the FDA's decision"); *see also Frater*, 996 F. Supp. 2d at 348-49 (E.D. Pa. 2014) (claim adequately pled that "Hemispherx systemically misled investors about the key components of the [ ] NDA and the nature of FDA

feedback while presenting predictions about FDA approval … that it should have known were unreasonable under the circumstances."); *Skiadas v. Acer Therapeutics Inc.*, 2020 WL 4208442, *8 (S.D.N.Y. July 21, 2020) (complaint upheld where "Defendants knew that the FDA had not *agreed* to approve EDSIVO but … chose to say the opposite."); *Gorlamari v. Verrica Pharm., Inc.*, 2024 WL 150341, *12 (E.D. Pa. Jan. 11, 2024) (falsity alleged where "White's partial response 'yes' could suggest that White had not received news inconsistent with approval in late May, which would contradict the FDA's findings in February 2022 that quality problems persisted.").[4]

4. The misstatements about non-manufacturing-related risks

The Complaint adequately alleges that the deficiencies Defendants hid from the market were far more likely to delay FDA approval than the hypothetical risks mentioned, *i.e.*, delays due to the coronavirus pandemic or other issues and the hypothetical possibility of regulatory violations or incomplete data from third-parties:

- 3/16/20: "Data provided by collaborators and others upon which we rely that has not been independently verified ***could*** turn out to be false, misleading, or ***incomplete***." Specifically, the 2019 10-K stated that "[w]e rely on third-party vendors, scientists, and collaborators to provide us with significant data and other information related to our projects, clinical trials, and business. ***If such third parties provide*** inaccurate, misleading, or ***incomplete data***, our business, prospects, and results of operations could be materially adversely

[4] Unlike in *In re Amarin Corp. Sec. Litig.*, 2016 WL 1644623 (D.N.J. Apr. 26, 2016), relied upon by Defendants (DM at 20-21), the FDA's concerns *did* put the DefenCath NDA "in jeopardy" as demonstrated by the First CRL. And such concerns were not related to something unique about DefenCath itself, but rather about the ability of the proposed manufacturing process to produce a consistent quantity and quality – something which is required of all FDA-approved drugs. Thus, Defendants' reliance on *Bauer v. Eagle Pharms., Inc.*, 2017 WL 2213247 (D.N.J. May 19, 2017), also fails.

affected." ¶190.

- 4/22/20: Approval was "subject … to possible delays at FDA due to the coronavirus pandemic." ¶¶96, 194.
- 5/12/22: CorMedix had minimized risk through "continuing initiatives to dual source key components and active ingredients in order to de-risk … potential governmental regulatory actions at any key supplier." ¶¶153, 276.
- 6/15/22: "[T]his is an inspection of facility that is larger than just the manufacturing operations related to DefenCath." ¶279.

Nowhere did Defendants disclose that CorMedix had not provided the necessary CMC data, had not ensured its CMO was cGMP compliant, or that these and other known CMC deficiencies put it at high risk of receiving a CRL rather than FDA approval.

Defendants' "risk disclosures" were not only ineffective, but themselves false and misleading as they affirmatively mischaracterized any "risks" to the DefenCath NDA as potential when the conditions they described had already come to pass.[5] *See In re Westinghouse Sec. Litig.*, 90 F.3d 696, 710 (3d Cir. 1996) ("to caution that it is only possible for the unfavorable events to happen when they have already occurred is deceit"). For example, Defendants claimed that "our contract manufacturers ***may not be able to comply with the applicable FDA regulatory requirements***, which could result in delays to our product development programs, could result in adverse regulatory actions against them or us, and could prevent us from ultimately receiving

[5] Defendant's reference to *Williams v. Globus Med., Inc.*, 869 F.3d 235 (3d Cir. 2017) (DM at 19, n.14) to assert that CorMedix's "risk disclosures" were truthful does not apply here. In *Globus*, the defendant had reason to believe that adverse effects were unlikely. *Id.* at 242-43. Here, adverse conditions had already materialized or were exceedingly likely to materialize.

product marketing approval." ¶191.

Defendants also spoke of adverse outcomes "***[i]f we and our contract manufacturers fail to achieve and maintain high manufacturing standards in compliance with cGMP****[.]*" *Id*. Deceitful "warnings" such as these create a duty to disclose and thus are not insulated as forward-looking. *See In re: Enzymotec Sec. Litig.*, 2015 WL 8784065, *15 (D.N.J. Dec. 15, 2015) ("Plaintiffs specifically allege that these risks had already come to pass and that it was therefore unreasonable to make generalized warnings when Defendants knew, or should have known, of the specific regulations and their likely effect."); *Strougo v. Mallinckrodt Pub. Ltd. Co.*, 2022 WL 17740482, *11 (D.N.J. Dec. 16, 2022) (same); *Viropharma*, 21 F. Supp. 3d at 471 (citing cases).

5. Defendants' misstatements and omissions are not protected opinions or forward-looking statements

Defendants argue that their false and/or misleading statements should be excused as expectational or "forward-looking." *See* DM at 24-28. They are wrong on the facts and the law. The Complaint does not allege that Defendants failed to correctly predict that the FDA would not approve DefenCath, but that Defendants concealed adverse events and risks that *had already occurred or were then in the process of occurring*.[6]

[6] *See*, *e.g.*, DM at 4, 26-27 (characterizing challenged statements as "corporate optimism"). Courts routinely reject identical attempts to mischaracterize complaint allegations. *Frater*, 996 F. Supp. 2d at 348-49 (Argument that plaintiff's claim turned on likelihood of approval "irrelevant to whether Hemispherx systemically misled

And the "safe harbor or bespeaks caution [doctrine] provides no protection to someone who warns his hiking companion to walk slowly because there might be a ditch ahead when he knows with near certainty that the Grand Canyon is one foot away." *In re Bristol-Myers Squibb Sec. Litig.*, 2005 WL 2007004, *52 (D.N.J. Aug. 17, 2005). As explained by Defendants' own case, *OFI Asset Mgmt. v. Cooper Tire & Rubber*, 834 F.3d 481 (3d Cir. 2018) (DM at 24), a "vague or blanket (boilerplate) disclaimer which merely warns the reader that the investment has risks will ordinarily be inadequate to prevent misinformation. To suffice, the cautionary statements must be substantive and tailored to the specific future projections, estimates or opinions in the documents which the plaintiffs challenge." *Id.* at 491.

Defendants' vague "cautionary language" did not describe the then-identified manufacturing issues, and therefore provides no cover for their misstatements. For example, in *In re Amarin Corp. PLC Sec. Litig.*, 689 F. App'x 124, 131-32 (3d Cir. 2017), relied on by Defendants (DM at 20), the Third Circuit applied cautionary language only where the statements themselves were alleged to be false based on

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investors about the key components of [ ] NDA and the nature of FDA feedback…."); *Shanawaz v. Intellipharmaceutics Int'l Inc.*, 348 F. Supp. 3d 313, 324-25 (S.D.N.Y. 2018) ("At issue here are not Defendants' opinions about the NDA's prospects before the FDA, but [their] allegedly false descriptions of the contents of the NDA itself."). Defendants' reliance on *In re Egalet Corp. Sec. Litig.* 340 F. Supp. 3d 479 (E.D. Pa. Aug. 2, 2018), *Eagle Pharm.*, 2017 WL 2213247 (D.N.J. May 19, 2017), and *Genzyme*, 754 F.3d 31 (1st Cir. 2014) to argue that their misstatements are forward-looking are also misplaced for the very reason stated above—the alleged false and misleading statements and omissions here relate to then-existing and known facts and conditions.

subsequent developments, rather than currently-existing facts, as here.[7]

Nor does including the word "expects" or "believes" transform statements made about information known to Defendants from the start of the Class Period into "forward-looking" statements. Where alleged misstatements addressed already-known issues, "it cannot be that the mere inclusion of 'words of futurity or belief' brings otherwise non-forward-looking statements within the PSLRA safe harbor." *Frater*, 996 F. Supp. 2d at 348; *see also Bristol-Myers*, 2005 WL 2007004, *24 (holding statement that trial results "are very impressive results" not puffery because they "refer[] specifically to the results from the [drug] trials—a matter of historical fact").[8]

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[7] Defendants' bid to contest materiality based on the supposed forward-looking nature of their statements (*see* DM at 24-25) is misplaced because, as discussed above, those statements were rooted in present fact.

[8] As the Supreme Court explained in *Omnicare Inc. v. Laborers Dist. Council*, liability is created when a statement "omits material facts about the issuer's inquiry into or knowledge concerning a statement of opinion, and…those facts conflict with what a reasonable investor would take from the statement itself." 575 U.S. 175, 189 (2015). And, because words like "we believe" and "we think" "can preface nearly any conclusion, … the resulting statements, as we have shown, remain perfectly capable of misleading investors." *Id.* at 193. In *Eagle Pharm.*, 2017 WL 2213147, cited by Defendants (DM at 24-25), the statements held to be puffery were found not to "relat[e] to FDA approval" and thus no rule was articulated which is relevant here. And while in *In re Aetna, Inc. Sec. Litig.,* F.3d 272 (3d Cir. 2010) and *Southeastern Penn. Transp. Auth. v. Orrstown Fin. Services, Inc.*, 2015 WL 3833849 (M.D. Pa. June 22, 2015) (DM at 25-27), the alleged misstatements were found to be puffery or immaterial as a matter of law because they were too oblique for reasonable investors to rely on them. Defendants' statements in this case were materially misleading in context, and relied upon by investors, because they sought to allay concerns about CorMedix's team and resources after Defendants publicly disclosed the FDA's request for more information and the First CRL. ¶¶186, 205, 213, 228, 235, 255, 260. That investors relied on the alleged misstatements and omissions is evidenced by the increases in CorMedix's stock price when the statements were made and the decreases when the truth became public.

C. Defendants' Scienter Is Adequately Alleged

To plead scienter, the PSLRA requires a plaintiff to allege facts which give rise to a strong inference that the defendant acted with the required state of mind in making misleading statements and/or omissions. 15 U.S.C. §78u-4(b)(2). In the Third Circuit, scienter is sufficiently alleged when the allegations give rise to a strong inference of "either reckless or conscious behavior." *See In re Advanta Corp. Sec. Litig.*, 180 F.3d 524, 534-35 (3d Cir. 1999). Recklessness encompasses "an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *Avaya*, 564 F.3d at 280 (quoting *Advanta*, 180 F.3d at 535). Conscious behavior, meanwhile, exists where a plaintiff "specifically allege[s] defendants' knowledge of facts or access to information contradicting their public statements." *In re Campbell Soup Co. Sec. Litig.*, 145 F. Supp. 2d 574, 599 (D.N.J. 2001).

In analyzing scienter, a court must determine "[w]hen the allegations are accepted as true and taken collectively, would a reasonable person deem the inference of scienter at least as strong as any opposing inference?" *Tellabs*, 551 U.S. at 326. That inference "need not be irrefutable, *i.e.*, of the 'smoking-gun' genre." *Id.* at 324. The analysis must be "case specific" and should "ultimately rest not on the presence or absence of certain types of allegations but on a practical judgment about whether, accepting the whole factual picture painted by the Complaint, it is at least as likely as

not that defendants acted with scienter."[9] *Avaya*, 564 F.3d at 269. The Complaint is clear that Defendants either knew of, or recklessly disregarded, the truth when making their false and misleading statements to investors during the Class Period.

1. That Defendants held themselves out to investors as having knowledge of the facts they misrepresented supports scienter

Each Defendant's scienter is supported by their respective claims to have knowledge of, and be authoritative sources to discuss, DefenCath's potential NDA and the FDA's support of that application in private regulatory communications. *See, e.g.*, ¶¶122, 178-79, 181, 183-84, 187, 190, 194, 196, 198-99, 201-03, 206-07, 209-11, 214-16, 219, 223-25, 227, 229-30, 232-34, 236, 239-40, 242-44, 246, 249-53, 256-59, 261, 266-68, 274.[10] That Defendants' "statements to investors … implied that they had first-hand knowledge" "bolster[s] the inference that [they] knew at the time that [their]

[9] For example, Plaintiff is not obliged to plead stock sales as a basis for scienter, as Defendants incorrectly suggest (DM at 11). *See In re Valeant Pharms. Int'l, Inc. Sec. Litig.*, 2017 WL 1658822, at *11 (D.N.J. Apr. 28, 2017) ("Because it is plausible that the Exchange Act Defendants were caught before they had a chance to sell their shares, the mere fact that the[y] did not sell their shares is insufficient to render Plaintiffs' allegations deficient."); *see also City of Warwick Ret. Sys. v. Catalent, Inc.*, 2024 WL 3219616, *13, *15 (D.N.J. June 28, 2024) (finding scienter adequately pled despite "no allegations that Defendants engaged in irregular stock sales or profited from the purported fraud."). Accordingly, Defendants' lack of stock sales do not exculpate them under a collective view of the alleged facts, and therefore have no impact on scienter. Defendants' reference to *In re Adolor Corp. Sec. Litig.,* 616 F. Supp. 2d 551 (E.D. Pa. 2009) (DM at 11) does not help them because the fatal flaw in the complaint there was that it failed to account for inconsistencies in defendants' withholding of information, not that defendants held onto their shares of stock. *Id*. at 571.

[10] These individually-made statements of implied knowledge undermine Defendants' unsupported assertion that "no individualized scienter allegations are made against Mr. Armstrong, Ms. Mounts, or Mr. Baluch" (DM at 12).

statements were false or was reckless in disregarding the obvious risk of misleading the public." *In re PTC Therapeutics, Inc., Sec. Litig.*, 2017 WL 3705801, *17 (D.N.J. Aug. 28, 2017). Thus, courts in the Third Circuit consistently find scienter where defendants hold themselves out as knowledgeable about the misrepresented topics. *See*, *e.g.*, *Catalent*, 2024 WL 3219616, at *14 (scienter properly alleged where individual defendants "spoke frequently about how involved they were in all aspects of the Company's business"); *see also Hall v. Johnson & Johnson*, 2019 WL 7207491, *22 (D.N.J. Dec. 27, 2019) (CEO who "repeatedly professed to have knowledge regarding" issues at the heart of alleged misstatements acted with scienter); *SEB*, 351 F. Supp. 3d at 906 (requisite scienter found where "officers were speaking as authoritative sources who possessed the information to support their statements").

Catalent is particularly instructive because the individual defendants, like Defendants here, misrepresented quality control weaknesses at an outsourced drug manufacturer. *See* 2024 WL 3219616 at *1. The *Catalent* court rejected defendants' claim that plaintiffs failed to allege what each individual defendant actually knew or did, citing their admitted "hands-on involvement" in the company, which included, *inter alia*, setting quality policies and standards, managing internal and external quality performance, evaluating the effectiveness of the design and operation of disclosure controls and procedures, attending to market concerns facing the company, and engaging with third-party vendors critical to the company's operations. *Id.* at *39-*40. That the Individual Defendants here repeatedly addressed those same topics throughout

the Class Period adds weight to Plaintiff's scienter allegations. *See, e.g.*, ¶¶122, 189-92, 224-25, 227, 229-30, 232-34, 239-40, 243-44, 246, 250-54, 257-59.[11]

Defendants not only spoke with authority about the DefenCath NDA, but provided responses to pointed questions and topics about DefenCath and its NDA process that gave investors the impression of knowledge. *See, e.g.*, ¶¶24, 226-27, 244-46, 259, 277. These exchanges strengthen the Complaint's strong scienter allegations. *See Roofer's Pension Fund v. Papa*, 2018 WL 3601229, *22 (D.N.J. July 27, 2018) (finding scienter in part based on defendants' "statements implying firsthand knowledge" and "their responses to specific questioning").[12] This is especially true regarding Defendants' characterizations of FDA feedback, implying their authority to speak on the FDA approval process. *See Frater*, 996 F. Supp. 2d at 349-50 (finding scienter where defendants conveyed FDA feedback to investors, thereby implying defendants were knowledgeable sources who knew the entirety of FDA feedback).

Defendants do not dispute making the statements the Complaint attributes to them, instead pointing to various details which have no bearing on scienter. *See* DM at 11-12. For example, the timing of Cook's employment at CorMedix does not detract

[11] Defendants wrongly claim that *Amarin*, 2021 WL 1171669 at *18, stands for the proposition that scienter cannot be inferred from any statements of implied knowledgeability. DM at 17. *Amarin* does not apply where the representations implicate FDA data, as they do here. *See PTC*, 2017 WL 3705801 at *19.

[12] Defendants' certainty when directly responding to analysts about potential FDA approval further bolsters scienter. *See Utesch v. Lannett Co., Inc.*, 385 F. Supp. 3d 408, 422 (E.D. Pa. 2019) (finding scienter when "a high-ranking officer evinces certitude as to a matter, particularly where the underlying substance is being publicly questioned").

from the strong inference of scienter that the statement attributed to him gives rise to, as it expressly described the FDA's purported support for the NDA and claimed to understand the FDA's next steps. *Compare* ¶178 *with* DM at 11. Likewise, the amount of description in the Complaint about David is irrelevant, because as Defendants acknowledge, he is alleged to have spoken on conference calls and signed SEC filings through which he held himself out as knowledgeable of the NDA's status and CorMedix's internal operations. *Compare* ¶¶140, 148, 204, 212, 231, 254 *with* DM at 11. Finally, that Todisco became CEO after the first CRL just means that his scienter is limited to subsequent misstatements and omissions concerning FDA inspections which resulted in CorMedix's *Second* CRL. *Compare* ¶33 *with* ¶¶35, 156, 274, 279.[13]

Defendants' respective professions of knowledge, taken together with the fact that their misstatements and omissions directly concerned the Company's core operations, demonstrates a strong inference of scienter. *See, e.g., Allegheny Cty. Emps.' Ret. Sys. v. Energy Transfer LP*, 532 F. Supp. 3d 189, 232-33 (E.D. Pa. 2021) (holding that the "core business doctrine has relevance as an additional source of support for the inference of scienter" where "some of the individual Defendants possesses personal

[13] Defendants also rely on *Acito v. IMCERA Grp., Inc.,* 47 F.3d 47 (2d Cir. 1995) to assert that scienter should not be inferred from Todisco's statements because it was not a "foregone conclusion" that the CMO would fail inspection or that "adverse consequences would ensue." DM 12. In *Acito*, however, the two prior failed FDA inspections indicated the plant was improving, and the plant represented a tiny fraction of the business. *Id.* at 52. Also unlike in *Acito,* the adverse consequences were foreseeable here as the 2018 audit report specifically stated that ROVI would not be able to pass an FDA inspection. *See* ¶¶5, 40, 80-87.

knowledge giving rise to a strong inference of scienter").[14]

2. Defendants' access to facts contradicting their public statements supports scienter

Scienter is adequately pled on conscious misbehavior grounds where a plaintiff "specifically allege[s] defendants' knowledge of facts or access to information contradicting their public statements." *Campbell Soup*, 145 F. Supp. 2d at 599; *see also Aldridge v. A.T. Cross Corp.*, 284 F.3d 72, 83 (1st Cir. 2002) (access to facts contradicting statements to investors is "classic evidence of scienter"). In this case, Defendants had access to the 2018 audit which flatly stated that ROVI would not be able to pass an FDA inspection (*see* ¶¶5, 40, 80-87) and had information regarding the First CRL, both of which they concealed from the investing public. *See* ¶24.

The Complaint's allegations about the 2018 audit are supported by statements from two former CorMedix employees (or "FEs"), one of whom drafted the 2018 audit report. ¶¶80-87. A securities fraud plaintiff "can support a complaint by reliance on information attributed to confidential source … in two situations: (1) if the complaint sets forth other factual allegations, such as documentary evidence, which are sufficient

[14] That Defendants' misrepresentations were directly related to the Company's core operations undermines their claim that Plaintiff failed to allege motive, which can be relevant to the holistic review of scienter, but is not required. *Avaya*, 564 F.3d at 276-277; *Tellabs*, 551 U.S. at 325 (holding that "the absence of a motive allegation is not fatal"). Nonetheless, Plaintiff does allege that Defendants had significant financial motives to hide material risks regarding the DefenCath NDA because the Company's survival virtually depended on it. ¶293. The Complaint further alleges that Defendants' false and misleading statements allowed CorMedix to raise tens of millions of dollars through secondary stock that it otherwise would not have been able to. ¶¶102, 134.

alone to support a fraud allegation, or (2) when the confidential sources are described in the complaint with sufficient particularity to support the probability that a person in the position occupied by the confidential source would possess the information alleged." *In re Intelligroup Sec. Litig.*, 527 F. Supp. 2d 262, 290 (D.N.J. 2007); *see also Nat'l Junior Baseball League v. Pharmanet Dev. Grp., Inc.*, 720 F. Supp. 2d 517, 538-39 (D.N.J. 2010). Both situations arise here: (1) the CRLs and other publicly-available information cited in the Complaint lend credibility to the FEs' statements; and (2) the FEs themselves are sufficiently described, likely to possess the information they discuss, and mutually-corroborative, *i.e.*, FE1 attests to the creation of the audit and FE2 attests to its contents. As such, this Court should credit their statements.[15]

[15] Notably, Defendants take no issue with FE1's statements. DM at 14. Nor do they explain why FE2, as Senior Director of Quality Assurance, would *not* have access to the audit report or why FE2 should be disbelieved for receiving the report *after* it was created. *Id.* Finally, that Defendants chose ROVI in 2017 is irrelevant; far more relevant is that CorMedix proceeded with ROVI despite the 2018 audit results *without* informing investors of the known, increased risk that the FDA would not approve the NDA. *That*, to answer Defendants' query, is "what the Company did in response to the audit." *Id.* As such, the cases Defendants cite in which a confidential source was not credited (DM at 13-14) are factually distinguishable. *See Chan v. New Oriental Educ. & Tech. Grp. Inc.,* 2019 WL 2865452, *11 (D.N.J. July 3, 2019) (CW worked at company four years prior to the class period and the "absence of facts about documents, dates, timing, or meetings … render[ed] the CW's statement deficient."); *Emps. Ret. Sys. of City of Providence v. Embraer S.A.*, 2018 WL 1725574, *10 (S.D.N.Y. Mar. 30, 2018) (plaintiff "relied exclusively upon general assertions about the [defendant]'s internal controls and … relate[d] them to the fact that some current [] employees knew about or participated in … ***pre***-Class Period bribery"); *Winer Fam Tr. v. Queen*, 503 F.3d 319 (3d Cir. 2007) (project leader's opinion did not give rise to scienter because there was no evidence that he conveyed opinion to defendant). Here, FE2 worked at CorMedix during the Class Period and provided sufficient facts about documents,

Next, the Individual Defendants' positions and responsibilities gave them access to knowledge that contradicted their public statements about DefenCath's FDA approval and manufacturing. *E.g.*, ¶¶294, 313, 316, 321, 323. This, in concert with the other scienter allegations, including that the misstatements and omissions concerned CorMedix's core operations, gives rise to the requisite scienter. *See SEB*, 351 F. Supp. 3d at 905-06 ("scienter may arise" by virtue of a defendant's position when the misstatements and omissions involved core matters of key importance to the company and its executives); *PTC*, 2017 WL 3705801 at *17 (same); *In re Genta, Inc., Sec. Litig.*, 2005 WL 2416970, *6-*7 (D.N.J. Sept. 30, 2005) (same) (collecting cases).[16]

A strong inference of scienter arises especially when a defendant is an executive and the core operations doctrine applies – which it does here, as discussed below. *See Industriens Pensionsforsikring A/S v. Becton, Dickinson & Co.*, 2021 WL 4191467, *19 (D.N.J. Sept. 15, 2021) ("'[S]tatus as a corporate officer, when considered

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dates, timing, and meetings. ¶¶82, 85, 104, 112. And FE1's 2018 audit and 2019 report, received by Defendants, connect to Class Period allegations both temporally and logically.

[16] Defendants' throwaway bid to contest scheme liability, DM at 29, also fails. Plaintiff alleges that Defendants concealed known deficiencies that had the effect of artificially inflating the Class Period price of CorMedix stock and in so doing, perpetrated a fraud upon the public. ¶¶178-280. Such allegations adequately state a claim for "scheme liability." *See In re ForceField Energy Inc. Sec. Litig.*, 2017 WL 1319802 (S.D.N.Y. Mar. 29, 2017) (holding allegations of stock price inflation via undisclosed purchases suffice to plead scheme liability). *SEC v. Mintz*, 2024 WL 1173096 (D.N.J. Mar. 18, 2024), cited by Defendants at DM 29 explains that an actionable scheme liability claim "requires something beyond misstatements and omissions, such as dissemination [of a false statement]. *Id.* at *15. That burden is easily met by Plaintiffs here.

alongside other allegations, can help support an inference that this person is familiar with the company's most important operations.'"). Likewise, in *In re Honeywell Int'l, Inc. Sec. Litig.*, the court found that a defendant who was both the company's CEO and Chairman should have full knowledge of its operations, and "[b]y virtue of his position he had to have known of the falsity of the representations he and his fellow officers made," establishing scienter. 182 F. Supp. 2d 414, 428 (D.N.J. 2002). Similarly here, as executives of CorMedix, the Individual Defendants had full knowledge of its operations and thereby knew the falsity of their representations to investors.[17]

3. The core operations doctrine supports scienter

"[M]aterial misrepresentations concerning core matters of central importance to a company may support an inference of scienter when accompanied by some additional allegation of specific information conveyed to management and related to the fraud." *Carmignac Gestion, S.A. v. Perrigo Co. PLC*, 2019 WL 3451523, *16 (D.N.J. July 31, 2019) (citing *Martin v. GNC Holdings, Inc.*, 757 F. App'x 151, 155 (3d Cir. 2018)). "Allegations that fraud related to a high-earning segment of a company have been found sufficient to support a core operations inference." *Id*. *See also Catalent*, 2024

[17] While Defendants contend that scienter cannot be established by the high-level nature of the Individual Defendants' positions within CorMedix, *see* DM at 17, courts in this district have rejected that argument, holding that allegations of a defendant's executive position providing "access to information contradicting [that his] public statements," taken together with other scienter allegations, suffice to create a strong inference of scienter. *See T. Rowe Price Growth Stock Fund, Inc. v. Valeant Pharms. Int'l, Inc.*, 2018 WL 395730, *6-*7 (D.N.J. Jan. 12, 2018).

WL 3219616 at *13 & n.23 (misstatements concerning "core matters of central importance" raised a strong inference of scienter).

As the Complaint notes, the adverse developments relating to the DefenCath NDA and at the CMO impacted the most central aspect, or core, of CorMedix's business, operations and revenue. ¶¶2, 37. This more than suffices to establish scienter under the core operations doctrine. *See*, *e.g.*, *Hall*, 2019 WL 7207491 at *21 (collecting cases and finding scienter where defendant considered the product at the heart of the misstatements a "flagship product"); *Carmignac*, 2019 WL 3451523 at *16 (finding scienter where the relevant section comprised 22% of defendant's business); *Enzymotec*, 2015 WL 8784065, at *17-*18 (finding scienter where the misstatements "about which Defendants regularly spoke" concerned their core business).

By contrast, *Industriens*, cited by Defendants, involved a product that was a fraction of a division that drove 50% of the business and there were no "other, individualized allegations that further suggest that the officer had knowledge of the fact in question." 2021 WL 4191467 at *19. The Complaint here involves CorMedix's flagship product and contains individualized allegations suggesting Defendants had, or should have had, knowledge about what the FDA was saying about the DefenCath NDA and what was going on at the Company's CMO. Finally, *Industriens* identifies a host of cases applying the core operations doctrine when, as here, the misstatements at issue "concern[ed] matters exceptionally impactful on the businesses at issue" and the

company's stock price declined significantly upon disclosure of the truth. *Id*. at *19 n.33. Thus, the core operations doctrine should apply here even under *Industriens.*[18]

4. Defendants Armstrong and Todisco's experience bolsters scienter

A defendant's experience can be used to show they knowingly misused industry terms or concepts to mislead investors. For example, a defendant's "background and experience in the pharmaceutical industry" strongly suggests they understand how statements regarding pharmaceuticals could be misconstrued and/or misleading, bolstering scienter. *See McDermid v. Inovio Pharms., Inc.*, 520 F. Supp. 3d 652, 654 (E.D. Pa. 2021).[19] Here, CorMedix touted Armstrong's 45+ years in the pharmaceutical industry, ¶52, and Todisco joined with 11+ years in the pharmaceutical industry, including as an executive, ¶54. Analysts described Todisco's "onboarding as a positive sign for CRMD and DefenCath" as they "expect[e]d [him] to have done a fair amount

[18] The other cases relied upon by Defendants which did not apply the core operations inference (DM 16) are likewise inapposite. *See Hoey v. Insmed Inc.*, 2018 WL 902266, *23 (D.N.J. Feb. 15, 2018) (plaintiff relied on an irrelevant document and meetings that could have plausibly occurred before the relevant drug trial relevant as support for core operations inference); *In re Heartland Payment Sys., Inc. Sec. Litig.*, 2009 WL 4798148, at *7 (D.N.J. Dec. 7, 2019 ("after-the-fact speculation by a handful of lower-level employees" did not support inference that corporate officers should have been aware of security concerns); *Advanta*, 180 F.3d 525, 539 (knowledge plaintiff alleged was not "undeniably… significant" to the company). Here, as detailed above, Plaintiff alleges that Defendants had access to relevant facts and considerable reason to be aware of deficiencies at the CMO, and that DefenCath was CorMedix's flagship product.

[19] Defendants cite *In re Synergy Pharms., Inc. Sec. Litig.*, 2021 WL 4480625, (E.D.N.Y. Sept. 30, 2021) (DM 16) for its analysis of industry experience and finding of no scienter, but on appeal, Synergy's CFO was found to have acted with scienter. *See In re Synergy Pharms Inc.*, 2023 WL 5526675, at *2 (2d Cir. Aug. 28, 2023).

of due diligence before deciding to join CRMD at such a critical juncture." ¶151.[20]

5. Defendants Baluch and David's SOX certifications bolster scienter

The already strong inference of scienter is supported by Baluch's and David's SOX certifications, which claim they each assessed Cormedix's disclosures and disclosure controls. ¶¶192, 204, 212, 231, 254. Courts in this Circuit have held that SOX certifications can *contribute* to a finding of scienter, *see In re Toronto-Dominion Bank Sec. Litig.*, 2018 WL 6381882, at *19 (D.N.J. Dec. 6, 2018), and they do so here.[21]

6. No plausible competing inference

Defendants do not attempt to raise a competing inference to explain why they hid adverse data and regulatory communications from investors. Their "non-culpable inference" is simply the strawman assertion that they "sincerely believed that DefenCath would be approved" (DM at 18). But that cannot serve as a competing inference to Plaintiff's well-pled allegations showing that Defendants knew of serious

[20] Conversely, the sudden October 4, 2021 departures of Armstrong and Baluch shortly after CorMedix's manufacturing woes began to become public (¶¶48, 52) augment their scienter. "A resignation may support a finding of scienter because it may be implied that the individual knew of the fraud being perpetrated. Once those outside the fraud find out, supposedly, they terminate (or force to resign) all those who may have been responsible." *Toronto-Dominion Bank*, 2018 WL 6381882, *18. In particular, CorMedix's statement made contemporaneously with the departures that it did not have the "right team" to resolve the deficiencies, ¶137, strongly suggests both Armstrong and Baluch had knowledge of and were involved in the manufacturing issues plaguing CorMedix.

[21] While Defendants claim the SOX certifications are inactionable opinions, relying on *In re Cognizant Tech. Solutions Corp. Sec. Litig.*, 2018 WL 3772675 (D.N.J. Aug. 8, 2018) (DM at 27), they are actionable here as they omitted then-known, existing facts.

risks to FDA approval but hid those *risks* from investors.

When the Complaint is considered as written, *Tomaszewski*, cited *supra*, is fully on point. There, as here, the defendant company: (1) "was struggling to survive," (2) had "only one viable drug candidate," (3) fast-tracked its drug's FDA approval, meaning that "changing course in reaction to FDA's feedback would have cost time and money," and (4) had executives who knew of potential issues, but nevertheless made statements expressing confidence in FDA approval. *Id*., 482 F. Supp. 3d at 330. As here, such facts support "a cogent and compelling inference that, in response to a time and money crunch, [defendants] took—and lost—a calculated gamble to initiate the preparatory work for the Phase 3 studies without FDA approval, and that when the FDA expressed disagreement, [defendant] deceived investors in the hope that the FDA would end up agreeing with the data from the Phase 3 studies and approve [the drug]." *Id*. at 333. While such a regulatory "Hail Mary" may make sense, if "Defendants misled [investors] about such risks by making assurances regarding the completeness of the data and likelihood of FDA approval, Defendants may be held liable." *Id*. at 335 n.100.

Similarly, the court in *Frater*, 996 F. Supp. 2d at 349, found the requisite scienter where "statements characterizing the feedback Hemispherx received from the FDA at the June 8 meeting imply that speakers knew the entirety of the FDA's feedback, including its concurrent warning that it would be unusual for a resubmitted NDA to succeed based on reanalysis of previously submitted data." And the court in *In re Viropharma, Inc. Sec. Litig.* found scienter where defendants were aware of issues with

Phase II trials but misrepresented them to investors. 2003 WL 1824914, at *9 (E.D. Pa. Apr. 7, 2003). As in *Tomaszewski*, *Frater* and *Viropharma*, these Defendants gambled that the FDA would look past the internally-known, but not publicly disclosed, risks posed by their CMO – only coming clean when no other option remained. ¶¶218, 281.

D. Loss Causation Is Adequately Alleged

The Supreme Court has made clear that alleging loss causation "should not prove burdensome" as a plaintiff need only "provide a defendant with some indication of the loss and the causal connection that the plaintiff has in mind." *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336, 347 (2005). And the Third Circuit instructed that loss causation inquiries are generally inappropriate on a motion to dismiss. *See EP Medsystems, Inc. v. EchoCath, Inc.*, 235 F.3d 865, 884 (3d Cir. 2000). Rule 9(b) and the PSLRA impose heightened pleading requirements of factual particularity on allegations of falsity and scienter, but not loss causation. *See Dura*, 544 U.S. at 347.

A "[p]laintiff may adequately plead loss causation by alleging either a corrective disclosure of a previously undisclosed truth that causes a decline in the stock price or the materialization of a concealed risk that causes a stock price decline." *In re Wilmington Tr. Sec. Litig.*, 29 F. Supp. 3d 432, 450 (D. Del. 2014); *see also McCabe v. Ernst & Young, LLP*, 494 F.3d 418, 425-26 (3d Cir. 2007) (holding loss causation can be proven where "defendant misrepresented or omitted the very facts that were a substantial factor in causing the plaintiff's economic loss," and materialization of the risk "is consistent with our loss causation jurisprudence."). Courts have recognized that

"***[t]he ultimate loss causation inquiry under either the corrective disclosure theory or the materialization of a concealed risk theory is the same***: whether a misstatement or omission concealed something from the market that, when disclosed, negatively affected the value of the security." *De Vito v. Liquid Holdings Grp., Inc.*, 2018 WL 6891832, *39 n.37 (D.N.J. Dec. 31, 2018).[22]

Here, Plaintiff easily met his burden of demonstrating "that the loss caused by the alleged fraud resulted from the relevant truth ... leak[ing] out." *Id*. The Complaint alleges that each corrective disclosure and risk materialization provided the market information previously concealed about the DefenCath NDA and was promptly followed by a decline in the price of CorMedix stock. *See* ¶¶178-280, 286-90. And for each disclosure, the Complaint reveals what new information was disclosed to the market and how it related to Defendants' prior concealment. *Id*. Thus, the Complaint not only satisfies, but exceeds, the "some indication" standard prescribed by *Dura*.

Defendants unpersuasively claim to have previously disseminated the facts Plaintiff alleges were concealed in order to liken this case to *Rice Revocable Fam. Tr. 5/9/90 v. Intercept Pharms., Inc.*, 2022 WL 837114 (S.D.N.Y. Mar. 21, 2022) (*see* DM at 28-29). But Plaintiff does not allege that revelations about boilerplate, general "risks

[22] District courts within this Circuit regularly accept the materialization of the risk theory. *See*, *e.g.*, *Wilmington Tr.*, 29 F. Supp. 3d at 450; *In re Urban Outfitters, Inc., Sec. Litig.*, 103 F. Supp. 3d 635, 657 (E.D. Pa. 2015) ("Plaintiff has adequately alleged a materialization of the concealed risk...."); *In re Galena Biopharma, Inc. Sec. Litig.*, 2021 WL 50227, *8 (D.N.J. Jan. 5, 2021) ("Plaintiffs have adequately pled loss causation through a materialization of the risk approach….").

inherent in the FDA approval process," *id.*, were what caused his losses. Rather, Plaintiff alleges that revelations about what led to each CRL caused his losses, all of which had been previously undisclosed to CorMedix investors. *See* ¶¶178-280; 286-90. No more is required at this stage. *See Catalent*, 2024 WL 3219616, at *15 ("[L]oss causation is adequately pled when a company's stock price declines after media reports and disclosures presented new information about the alleged fraud to the public.") (citing cases). And Defendants' truth on the market defense fails. *See Roofer's*, 2018 WL 3601229, at *9 (requiring defendants to "convey[] to the public with a degree of intensity and credibility sufficient to counter-balance effectively any misleading information created by the alleged misstatements" to prevail at motion to dismiss).

Finally, Defendants' creative reimagining of the September 7, 2021 disclosure (DM at 28) merely raises a factual dispute to be resolved by the jury. For pleading purposes, the Court must accept Plaintiff's well-pleaded allegations as true and draw inferences in his favor. *See Fleisher*, 679 F.3d at 120. That the delays emanated from the same defective facility at the heart of the FDA's rejection of DefenCath is enough; if Defendants have any competing evidence, they may present that evidence at trial.

CONCLUSION

Based on the foregoing, Defendants' motion should be denied in full. If the Court finds any deficiency in the Complaint, Plaintiff respectfully requests leave to amend.[23]

[23] Defendants' §20(a) argument (DM at 30) fails because Plaintiff adequately pled a predicate §10(b) violation, thus the §20(a) violation was adequately alleged as well.

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Respectfully Submitted,

POMERANTZ LLP
/s/ *Louis C. Ludwig*
Joshua B. Silverman (*pro hac vice)*
Louis C. Ludwig (NJ 043582008)
10 South LaSalle St., Ste. 3505
Chicago, IL 60603
Telephone: (312) 377-1181
jbsilverman@pomlaw.com
lcludwig@pomlaw.com

FREEDMAN NORMAND FRIEDLAND LLP
Ivy T. Ngo (*pro hac vice*)
Velvel (Devin) Freedman (*pro hac vice*)
1 SE 3rd Ave., Suite 1240
Miami, Florida 33131
Telephone: (786) 924-2900
ingo@fnf.law
vel@fnf.law

Counsel for Lead Plaintiff and the Class

THE SCHALL LAW FIRM
Brian Schall (*pro hac vice* forthcoming)
1880 Century Park East, Suite 404
Los Angeles, CA 90067
Telephone: (424) 303-1964
brian@schallfirm.com

BRONSTEIN, GEWIRTZ, & GROSSMAN, LLC
Peretz Bronstein
Eitan Kimelman
60 East 42nd Street, Suite 4600
Telephone: (212) 697-6484
peretz@bgandg.com
eitank@bgandg.com

Additional Counsel for Lead Plaintiff

CERTIFICATE OF SERVICE

I hereby certify that on July 22, 2024, a copy of the foregoing was filed electronically via the Court's CM/ECF system. Notice of this filing will be sent by e-mail to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's CM/ECF System.

POMERANTZ LLP

By: */s/ Louis C. Ludwig*
Louis C. Ludwig
Counsel for Lead Plaintiff